

REMARKS

I. OVERVIEW

Claims 1-15 are pending in this application. Claims 11-15 are withdrawn from consideration pursuant to Applicants' provisional election made on July 20, 2007 to prosecute the invention of Group I, claims 1-10. Claims 1-10 are rejected under 35 U.S.C. §103(a) as obvious. The Examiner also objects to the title of the invention as non-descriptive as it does not clearly indicate the claims to which the invention is drawn. The Examiner also objects to the drawings submitted by Applicants on February 6, 2004, but fails to provide any reason for the objection. Therefore, no new drawings have been submitted.

II. ELECTION/RESTRICTION

The Examiner has required that Applicants restrict the invention to one of the following inventions under 35 U.S.C. § 121:

- I. Claims 1-10, drawn to a method of immunization identification, classified in class 604, subclass 500.
- II. Claims 11-15, drawn to an immunization identification system, classified in class 40, subclass 638.

The Examiner further states that the inventions are distinct from each other as they are related to both a product and a process of use. The Examiner even further states that the inventions are distinct as the process for using the product can be practiced with another materially different product or the product could be used in a materially different process of using that product. Even further the Examiner states there would be a serious burden if restriction were

not required because the inventions have separate status in the art, in view of their of their different classifications.

Applicants provisionally elected Group I, claims 1-10 during a teleconference on July 20, 2007. Applicants maintain the provisional election of Group I, claims 1-10, and withdraws claims 11-15. The election in reply to the Examiner's restriction requirement is hereby made with traverse. The claims in Group I and Group II contain the same limitations and scope as each other with respect to each and every claimed element. Despite the different classification as products and process of use claims and the Examiner's identification of different statutory classes and subclasses for the inventions, no additional burden is placed on the Examiner to search for the product and process of use claims.

III. AMENDMENT TO SPECIFICATION

The Examiner states that the title of the invention is not descriptive and a new title, clearly indicative of the invention to which the claims are directed, is required. The Examiner further suggests the title: "A Universal Method of Immunization Identification." Applicants have amended the specification to comply with the Examiner's requirement that a new title be indicative of the claimed invention. Applicants have selected the title "Universal Comprehensive Immunization Identification Method" pursuant to the Examiner's suggested language.

IV. CLAIM REJECTIONS UNDER 35 U.S.C. §103

A. Claims 1-3 and 6-9 Rejected under 35 U.S.C. § 103 over Hall and Walsh

The Examiner has rejected claims 1-3 and 6-9 under 35 U.S.C. § 103(a) as being unpatentable over Hall (U.S. Patent Publication 2004/01458186) in view of Walsh (U.S. Patent

No. 6,464,136). Applicant respectfully traverses these rejections and requests reconsideration of the claims.

The Examiner states that Hall describes an adhesive bandage that can be used for the identification of a vaccine administered at an injection site; specifically, Hall describes a method of vaccination comprising administration of a vaccine by injection into a recipient at a vaccination site and the application of adhesive bandage to the vaccination site (page 2, claim 11). The Examiner admits that Hall fails to teach the application of a colored adhesive-backed strip to a syringe and the application of another color adhesive-backed strip to a medical chart of a patient. However, the Examiner then concludes that Walsh in light of Hall describes the method for verification of the identity of a patient undergoing medical treatment, and it would have been obvious to a person having ordinary skill in the art to incorporate the teachings of Walsh to the teachings of Hall because doing so would facilitate verification of a patient undergoing a medical treatment, such as an immunization, and would avoid unnecessary medical error.

The Examiner further states in regard to claim 2, that the same method of immunization as claim 1 with the addition of a second immunization dosage is also disclosed by Hall (page 3, claim 13) stating that "at least two different vaccines are separately and concurrently administered to the intended recipient with separate adhesive bandages being applied to each vaccination site." Therefore, it would have been obvious to one of ordinary skill in the art, with the teachings of Hall and Walsh, that the method of the administration of the first immunization dosage and application of labels is the same as the method in administration of the second immunization dosage and application of labels. The Examiner further states in regard to claim 3, that a person having ordinary skill in the art in light of both Hall and Walsh that an identifier

carrying labels could be applied to "a patient identifying member" such as "a patient treatment chart". There is no differentiation between a patient treatment chart and a medical record according to one having ordinary skill in the art.

The Examiner further states in the rejection of independent claim 6, combining Hall and Walsh would have been obvious to one of ordinary skill in the art that if the labels are identical, they must have a common indicia, as claimed by the present invention. The Examiner also asserts that it would have been obvious to apply the teachings of Hall in order to set up a group of similar labels that can be applied to all the apparatuses used in a single immunization procedure. The Examiner continues in regard to claim 7, that it would have been obvious to expect that a second immunization would also have a set of similar identification labels in comparison to those of a first immunization. The Examiner again states that the administration of at least two vaccines to one patient is suggested by Hall (page 3, claim 13). The Examiner further states in regards to claim 8, that Hall (page 2, claims 1-3) teaches that different forms of indicia, including color, are used to identify different vaccines. The Examiner states further in regards to claim 9 that application of stickers to a home chart of the patient is rendered obvious according to the "patient treatment chart" mentioned in Walsh.

The Examiner's combination of Hall and Walsh fails to meet each of the limitations of the present invention. Hall merely identifies the application of an adhesive bandage to a vaccination site. Although the Examiner claims that the bandage disclosed in Hall displays indicia that identify the vaccine that was administered, it fails to identify and correlate all of the information which the present method claims achieve.

More particularly, independent claims 1 and 6 require the method of applying corresponding adhesive-backed strips, all having the same color, to first the syringe, then the

injection site on the patient, and a medical office chart. Each of these stickers are used to provide readily available identification of not only which vaccination has been administered to a patient, but also where it was administered, by route it was administered, from which vial it was administered, and then document all such information in a plurality of documenting means. The present invention goes beyond merely identifying the type of immunization administered to a patient and placing such records in a chart. Thus, this claimed invention solves a long-felt need, that is, inadvertent mistakes that happen in doctor offices for various reasons, as described in pages 1-2 of the Specification.

In KSR International Co. v. Teleflex, Inc., 127 S.Ct. 1727 (2007), the U.S. Supreme Court set forth several tests for obviousness. For example, one way to prove obviousness is by noting that there existed at the time of the invention a known problem for which there was an obvious solutions encompassed by the claims; and where there is a design need or market pressure to solve a problem, and there are a finite number of identified, predictable solutions, it is obvious for a person of ordinary skill in the art to pursue the known options within their technical grasp. Id. 1741-42. Here, there is a known problem of innocent errors being made in medical injections and documentation processes. However, the solution has not previously been obvious, since such errors still arise despite the wide spectrum of prior art. Also, there admittedly is a need to solve this problem, but there is not a finite number of identifiable, predictable solutions, or known options. Accordingly, Applicants' claimed invention does not meet the obviousness tests of KSR. As the Court in KSR acknowledged, merely demonstrating that each element of a combination is known in the prior art does not constitute obviousness. Id. at 1741.

Applicants have amended independent claims 1 and 6 to more clearly illustrate that the method of immunization identification includes the use of adhesive-backed stickers containing a

color and/or an identical indicia from a single immunization identification strip, coordinating to the first syringe used, the first injection site, and medical office chart. Each of the steps in the immunization process are identified by using an adhesive-backed sticker obtained from the common immunization identification strip coordinating with the immunization being administered. Thus, each immunization identification strip contains the series of stickers to be utilized by the healthcare professional. Accordingly, when a second immunization dose is prepared, an adhesive-backed sticker with a different color or idicia is obtained from a different and second immunization identification strip containing a second series of stickers, as required by claims 2 and 7. Claims 3 and 9 extend the method by requiring application of another sticker from the same strip to the patient home chart. Applicants' invention of the same colored stickers on one strip, and different colored stockers on another strip provides quick and easy visual verification of the immunization at various sites, contemporaneously with the injections, as well as at later times, so as to eliminate or minimize mistakes by healthcare personnel. The cohesive method set forth in the present invention connects each and every step of the process in a manner that is efficient, follows safety standards, and reduces liability as it minimizes errors and improves documentation.

The Examiner asserts that Walsh focuses on providing a "patient identification member" in order to identify a patient and their treatments through the use of either a syringe, drug label, container, etc. Moreover, this "patient identification member" could be a treatment chart. However, the modification of Hall in view of Walsh, as suggested by the Examiner, still fails to combine the claimed steps in an obvious manner in that the application of the adhesive-back stickers coordinates as each sticker from the same strip is applied to a syringe, an injection site after the injection, and the medical chart of the patient.

Applicants have also included a Rule 132 Declaration attesting to the praise and acclaim received by those skilled in the applicable art relating to the Universal Comprehensive Immunization Identification Method. The evidence contained therein has been timely filed and therefore should be entered and entitled to consideration in order to overcome the rejection of obviousness under 35 U.S.C. § 103. MPEP 716.01(a); In re Rothermel, 276 F.2d 393, 125 U.S.P.Q. 328 (C.C.P.A. 1960). The evidence contained in the 132 Declaration is relevant secondary indicia of non-obviousness, as those skilled in the pertinent art have given great acclaim and praise to method of the present invention. See e.g., Graham v. John Deere Co., 383 U.S. 1, 148 U.S.P.Q. 459 (1966). The statements by these medical professionals are strong evidence of non-obviousness, in that the prior art has not solved the problems in the medical field, which are solved by the invention.

As amended, the claims as presented obviate the Examiner's § 103 obviousness rejection of Hall and Walsh, as each of the limitations are not identified, suggested or taught in the prior art. Therefore, it would not have been obvious for one of ordinary skill in the art to practice the present invention. Reconsideration and passage to issuance are respectfully requested.

V. CONCLUSION

In light of the Applicants' amendments and remarks contained herein, as well as the Rule 132 Declaration, reconsideration and allowance is respectfully requested.

Please consider this a Request for a One-Month Extension of Time from November 23, 2007 to December 23, 2007 and charge Deposit Account No. 26-0084 the amount of \$60.00 for this extension.

No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,



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Enclosure: Rule 132 Declaration